REMARKS

Claims 217-218, 220-221, 223-227, 229-235, 237-238, and 240-241 are pending in the application. The amendments to the claims were made to further clarify the presently claimed invention. No new matter has been inserted into the application.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 217-218, 220-221, 223-235, 237-238, and 240-241 have been rejected under 35 U.S.C. §112, Second Paragraph, as being indefinite. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

It is believed that the presently amended claims are definite.

Rejection Under 35 U.S.C. §102(e) Over Bamdad '617 (US 6,541,617)

Claims 225-227, and 230-231 have been rejected under 35 U.S.C. §102(e) as being anticipated by Bamdad '617. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

The Office did not reject claim 228. In the interest of furthering prosecution toward an allowance, Applicant has amended independent claim 225 with the language of claims 228. Accordingly, it is believed that this rejection is overcome by the amendments to claim 225 (as well as claims dependent therefrom).

Rejection Under 35 U.S.C. §103(a) Over Bamdad '617 in view of Charych '556 (US 6,001,556)

Claim 217, 218, 223, 225-228, 230, 231, 233-235, and 240 have been rejected under 35 U.S.C. §103(a) as being "obvious" over Bamdad '617 in view of Charych '556. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Bamdad '617 discloses particles with bound ligands and electron transfer moieties. However, Bamdad '617 fails to disclose or suggest providing an agent linked to a non-colloidal structure and a binding partner of the agent linked to the colloid particle, and wherein the agent

acts as intermediary to the binding between the colloid particle and the non-colloidal structure as well as a drug screening method.

Charych discloses a lipid bilayer with affinity to an analyte, which directly signals binding by a changes in the light absorption spectra of the lipid bilayer.

However, Charych fails to disclose or suggest drug screening in a competitive assay compared with the methods of the claimed invention. Charych discloses using a lipid bilayer which is impregnated with a dye that signals one way when the bilayer is unperturbed but then, if a binding partner binds to it causing the bi-layer to be perturbed, then its signal changes. Therefore, there are at least two differences between Charych and the claimed invention.

First, in order to practice the Charych method the binding of the ligand to the lipid must be prevented because once the bilayer is perturbed, the bi-layer will not go back to its original state. Thus, the Charych method looks for interruption of binding before the interaction between the binding partner on the colloid and its ligand on the surface occurs. In addition, Charych looks for less signal and the Charych method does not look for reversal of the signal.

Second, Charych discloses that its method is appropriately useful for situations where the binding partner or the ligand is a small molecule that is synthesized on the end of the lipid chain and then is incorporated into the surface so that one of the binding pair - either the ligand or the receptor - is synthesized as the non-colloidal surface itself. Based on this disclosure, the Charych method a binding partner simply cannot be attached to the non-colloidal surface in order to conduct drug screening.

In the Charych reference, the binding partner on the lipid bilayer must be a small molecule by necessity because only small molecules can be engineered into a lipid bilayer. The engineered fatty acids are synthesized and are then mixed together to form the lipid bilayer. Therefore, these small molecules that are engineered into the lipid bi-layer cannot be proteins or biological molecules. Proteins are not and cannot be synthesized together with the fatty acids.

Charych discloses a method for screening for a drug by somehow preventing known binding of a receptor and a target. However, once the binding has occurred, the Charych method does not allow for any competitive binding away of the receptor. For instance, if there is a binding between cylic acid on the fatty acid and its natural binding partner such as hemagluttinin,

there is already an irreversible destruction caused on the bilayer membrane. In contrast, the inventive assay uses a candidate drug that disrupts or competes away the ligand and competes away the signal even after the binding between the ligand and its binding protein has occurred, which is assayable.

Given the above analysis, it is clear that Bamdad '617 fails to be combinable with Charych '556. Whereas colloids and nanoparticles and so forth are described in the Bamdad '617 reference, Charych '556 discloses receptor-ligand interactions that do not work for proteins on the membrane as either a ligand or receptor. The Examiner has cobbled together two references, which are wholly unrelated to each other, one in the field of nanoparticles and one in the field of biological assays, and made an obviousness rejection based on hindsight. As these references fail to be combinable with each other the presently claimed invention is not obvious over the cited references.

Even if *arguendo*, the references were to be hypothetically combinable, neither reference provides any motivation to combine the references to arrive at the claimed invention. Charych '556 fails to disclose or suggest using colloid particles in any of its methods. And Bamdad '617 fails to describe or suggest using the colloids for any drug screening assay. Therefore, the claimed invention is not obvious over the cited references.

Moreover, even if the references were combined, the result is not a competitive binding assay as in the claimed invention. Rather, the end result is an odd mixture of a lipid bilayer with affinity to an analyte, which directly signals binding by changes in the light absorption spectra of the lipid bilayer, and somehow inert use of colloids in this process, whereupon the signal generated from the colloid may interfere with the light signals from the lipid. Accordingly, the presently claimed invention is not obvious over the cited references.

Rejection Under 35 U.S.C. §103(a) Over Bamdad '617 in view of Charych '556, and Altieri '389 (US 6,346,389)

Claims 220, 229, and 237 have been rejected under 35 U.S.C. §103(a) as being "obvious" over Bamdad '617 in view of Charych '556 and Altieri '389. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Bamdad '617 is discussed above.

Charych '556 is discussed above.

Altieri '389 discloses Glutathione-S-Transferase fusion protein. Applicant asserts that in view of the fact that Sigal '670 fails to disclose or suggest a signaling entity other than an electroactive molecule or electrochemiluminescent moiety, which deficiencies are noted above, fails to be combinable with the Altieri '389 references that discloses the well known Glutathione-S-Transferase protein to arrive at the presently claimed invention which uses signaling entities that are not electroactive molecules or electrochemiluminescent moieties.

However, in view of the comments above regarding the non-obviousness of the claimed invention over the Bamdad '617 and Charych '556 references, it is believed that the rejection of the claims herein have also been overcome. Therefore, the presently claimed invention is not obvious over these cited references.

Rejection Under 35 U.S.C. §103(a) Over Bamdad '617 in view of Charych '556, and Zeytinoglu '539 (US 6,080,539)

Claims 221 and 238 have been rejected under 35 U.S.C. §103(a) as being "obvious" over Bamdad '617 in view of Charych '556 and Zeytinoglu '539. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Bamdad '617 is discussed above.

Charych '556 is discussed above.

Zeytinoglu '539 discloses detecting antibody/antigen reactions.

However, in view of the comments above regarding the non-obviousness of the claimed invention over the Bamdad '617 and Charych '556 references, it is believed that the rejection of the claims herein have also been overcome. Therefore, the presently claimed invention is not obvious over these cited references.

Rejection Under 35 U.S.C. §103(a) Over Bamdad '617 in view of Charych '556, and Virtanen '349 (US 6,342,349)

Claims 224, 232 and 241 have been rejected under 35 U.S.C. §102(a) as being obvious over Bamdad '617 in view of Charych '556 and Virtanen '349. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Bamdad '617 is discussed above.

Charych '556 is discussed above.

Virtanen '349 discloses an optical disk-based assay device in which analyte-specific signal elements are disposed on an optical disk substrate.

However, in view of the comments above regarding the non-obviousness of the claimed invention over the Bamdad '617 and Charych '556 references, it is believed that the rejection of the claims herein have also been overcome. Therefore, the presently claimed invention is not obvious over these cited references.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. **502486** for any fees required under 37 CFR § 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. **502486**.

Respectfully submitted,

JHK Law

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